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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,093	09/29/1999	KAZUHIRO OHSUYE	001560-373	5533

21839 7590 02/02/2006

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(INCLUDING BURNS, DOANE, SWECKER & MATHIS)  
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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/402,093

Applicant(s)

OHSUYE ET-AL.

Examiner

Elizabeth Slobodyansky, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 54-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 54-97 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The amendment filed November 8, 2005 amending claims 82-93 has been entered.

The substitute Sequence Listing and the computer readable form thereof filed July 5, 2005 have been entered.

The substitute specification filed July 5, 2005 has been entered.

Claims 54-97 are pending.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claim 54-81 and 94-97, in the reply filed on November 8, 2005 is acknowledged. The traversal is on the ground(s) that the restriction between Group I, claims 54-81 and 94-97, drawn to an expression vector encoding a fusion protein and a method of use thereof for producing a peptide of interest, and Group II, claims 82-91 and 93, drawn to a fusion protein, is improper (Remarks filed November 8, 2005, page 9).

It is noted that amended claims 82-91 and 93 are drawn to a process and therefore, the restriction is moot. Applicants further argue "The amendments result in the product claims depending from the process claims. Applicants note that the product claims have been elected. Applicants assert that should the product claims be found allowable, at the very least, the process claims should be rejoined with the product claims. See M.P.E.P. §§ 821.04 and 806.05(i)" (page 10). This is not found persuasive because absent the product claims, there is no restriction between the product and the process.

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"With respect to the species election, applications provisionally elect SEQ ID NO: 27 as the species for search purposes only and with traverse. Applicants make the election only to be fully responsive to the Official Action. Applicants assert that the species election requirement is improper. Applicants note that the Office has required Applicants to elect one of SEQ ID NOS: 5, 8, 21, 22, 23, 27, 28, and 70. Applicants note that SEQ ID NOS: 5 and 8 are directed to helper peptides, SEQ ID NOS: 27 and 28 are directed to peptides of interest, and SEQ ID NOS: 21 and 23 are directed to fusion proteins. Thus, to be forced to elect one species, in the event that the Office deems that one species to be obvious, Applicants would be left with the result of a claim that no longer reflects the currently claimed invention, because it would omit two other categories of Sequences" (page 10).

It is noted that before the amendment of 11/8/05, it was unclear which sequences represent fusion proteins, peptides of interest, helper peptides, etc. In order to include all three categories of the sequences discussed by Applicants above, the following election of species is required:

Claims 54-97 are directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Fusion proteins of SEQ ID NOS :20, 21, 22, 23. Claims drawn to helper or protective peptides will be examined with the elected fusion protein if said fusion

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protein comprises thereof. Applicants are requested to indicate protective and helper sequences within the elected fusion protein. For example, if applicants elect the fusion protein of SEQ ID NO:20, they should indicate that it comprises the helper peptide of SEQ ID NO:X, and the peptide of interest of SEQ ID NO:Y. Claims reciting said sequences such as claim 90 or claim 91, for example, will be examined together with the elected fusion protein.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 54-81 and 97.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they represent the fusion proteins having different structures and activities and therefore producing different effects.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Sequence Listing***

The Sequence Listing filed July 5, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the Sequence Listing filed July 5, 2005 contains sequences that are amended compared with the previous version of the Sequence Listing. For example, SEQ ID NO: 20 differs from SEQ ID NO:20 in the previous Sequence Listing filed June 7, 2002 by a single substitution E81D.

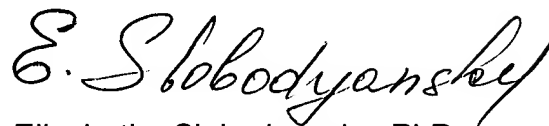
Applicant is required to cancel the new matter in the reply to this Office Action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth Slobodyansky, PhD  
Primary Examiner  
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January 25, 2006